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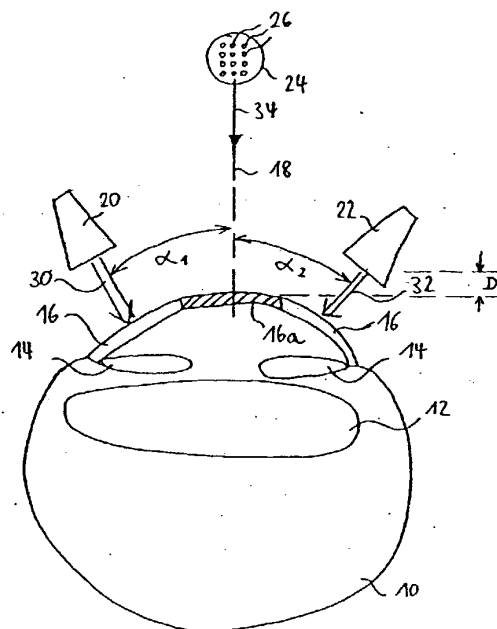
DEVICE FOR THE MEDICAL TREATMENT OF THE EYE BY MEANS OF  
A LASER BEAM

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The following statements are taken [unedited] from the documents submitted by the applicant.

[Abstract]

A device for the medical treatment of the eye by means of a laser beam uses an auxiliary beam to determine the ocular position. Using the auxiliary beam, pictures are taken with a solid-state camera to determine eye movements and to subsequently use the treatment laser beam to follow these eye movements. Infrared radiation sources which are positioned in a triangle over the eye to be treated are used for the auxiliary beam.



### Description

The subject matter of this invention concerns a device for the medical treatment and/or surgery of the eye by means of laser radiation using an auxiliary beam to determine the ocular position.

This type of device can be used especially for the so-called PRK procedure (photo-refractive keratectomy), i.e., a procedure for correcting visual defects of the human eye, during which especially the cornea is reshaped. The device according to the present invention is especially suitable for use in the so-called LASIK procedure in which first a small flap (lidlike cover) of epithelium, Bowman membrane, and stroma is cut and reflected to the side, and PRK is subsequently performed in the bed of the stroma.

It is a well-known fact that when treating the human eye by means of a laser, it is possible to use different types of lasers which, in the context of the present invention are especially excimer lasers (with a wavelength of, e.g., 193 nm) or Er:YAG solid-state lasers.

During PRK (in particular LASIK), material is removed from the cornea. This ablation is a function of the energy density (energy per unit of area) of the laser beam impinging on the cornea. Different techniques for shaping and focusing the beam are known, for example, so-

called slit scanning, in which the radiation is scanned by means of a moving slit across the surface that is to be treated; so-called spot scanning in which a scanning spot of very small dimensions is moved across the surface that is to be ablated; and so-called wide-field ablation (full ablation) in which the beam is guided over the entire surface that is to be ablated and in which the energy density changes along the profile of the beam in order to achieve the desired removal of the corneal layer. In prior art, all of the different beam focusing techniques mentioned above utilize suitable algorithms for controlling the radiation in order to remove the surface of the cornea in such a way that the cornea ultimately acquires the radius of curvature desired.

The spot scanning technique mentioned earlier (which uses a scanning spot) avails itself of a laser beam which is focused on a relatively small diameter (0.1 to 2 mm) and which, by means of a beam focusing device, is directed to different regions of the cornea and which is successively moved using a so-called scanner so that the desired ablation of the cornea is achieved. For the PRK and the LASIK technique, in particular so-called galvanometric scanners can be used (see article by G. F. Marshall IN LASER FOCUS WORLD, June 1994, p. 57). The present invention relates especially to the so-called spot scanning during the LASIK procedure.

A special problem that besets the PRK and LASIK procedures is the positioning of the laser beam relative to the eye. For medical reasons, a mechanical fixation of the eye is unsatisfactory. For this reason, prior art uses a so-called optical fixation in which, as a rule, a so-called fixing beam is coaxially used with the material-ablating laser beam. The patient is asked to look at exactly the spot defined by the fixing beam to ensure that the eye always occupies the same position during the entire operation. This, however, is most often not successful or is at least not reliable enough so that eye movements take place which are able to significantly impair the entire ablation procedure.

In prior art, a number of different devices are known, for example, so-called "eye trackers," i.e., devices which measure the movements of the eye and subsequently follow (track) them with the laser beam that is used for the ablation. This prior art technique is described, for example, in the following documents:

Pier Giorgie Gobbi et al.: Automatic Eye Tracker for Excimer Laser Photorefractive Keratectomy; Supplement to the Journal of Refractive Surgery, Vol. 11, May/June 1995; J. T. Lin: Ophthalmic Surgery Method Using Non-Contact Scanning Laser, U. S. Patent No. 5,520,679, May 28, 1996; and Fabrice Manns et al.: Optical Profilometry of Poly(methylacrylate) Surfaces After Reshaping With a Scanning Photorefractive Keratectomy (SPRK) system, Journal of APPLIED OPTICS, Vol. 35, No. 19, July 1, 1996.

Reference is also made to the German Utility Model Patent No. 298 09 759.1. In this patent, white light which is emitted by light emitting diodes is used for the auxiliary beam which serves to determine the ocular position for "eye tracking."

The German Patent No. DE 197 02 335 C1 describes a laser system for the treatment of the cornea by means of devices which track the movement of the eye relative to a reference axis and correspondingly control the laser treatment beam. For this purpose, an image-taking device (CCD camera) is used, and an auxiliary beam is used to illuminate the eye to produce the images. In correspondence with a movement of the eye relative to the reference axis, a control guides a beam focusing device, e.g., a galvanometric scanner. For the image sequence rate with which the camera takes pictures, a specific function relative to the pulse sequence rate of the laser beam is proposed. It is taken for granted that this prior art is known and used. But to summarize briefly, prior art teaches to use a camera to take a rapid sequence of images of the eye and to process these images to determine the movements of the eye. A change in the position of the eye (pupil position) can subsequently be determined from successive images (e.g., two successive images). The ablation laser beam can subsequently be controlled in correspondence with the eye movement by means of suitable beam focusing devices (e.g., the so-called galvanometric scanner).

Thus, in PRK (in particular in LASIK), a minimum of three different types of radiation are distinguished. First, the actual treatment laser beam which is responsible for the ablation of an area of the corneal layer; secondly, the so-called auxiliary beam, i.e., the beam which serves to illuminate the eye so as to make it possible to determine the position of the eye, e.g., by means of a camera, and thirdly, if desired, the so-called fixing beam which is stationary and which serves to help the patient to keep looking at the same spot (the latter represents only a special option).

In prior art, halogen lamps which are introduced into the observation beam path by means of a fiber bundle are used to fully illuminate the eye. Prior art also includes the use of an annular lamp or the coaxial incorporation of the illuminating beam via a surgical microscope. Also known are flexible swan neck lamps for positioning the illuminating light so as to fully illuminate the anterior area of the eye, in particular the cornea, to enable the ophthalmologist to optionally adjust the light for an optimum observation of the eye as a whole. It is desirable to improve the tungsten halogen lamps and xenon lamps used in prior art, both for the sake of reducing the stress on the patient and for providing the treating physician with a better quality of illumination.

If, in particular, during the spot scanning procedure for LASIK, the iris and the pupil are photographed with a camera system to determine the ocular position and if subsequently the center of gravity of the pupil is calculated (on-line), a high contrast between the pupil and the iris is required to optimally identify the pupil. It was found that relative to the angle at which the beam impinges, the wavelengths, etc., the auxiliary beam is essential to obtain satisfactory result when determining the ocular position.

Thus, the problem to be solved by the present invention is to make available a device for the medical treatment of the eye of the type described in the introduction which ensures that during the determination of the ocular position, reliable results are obtained, in particular if the system is used for different eyes (patients) and under different conditions.

Solutions to the problem according to the present invention are described in the claims below.

The present invention is based on the recognition that especially good measuring results with respect to the ocular position are obtained if a minimum of two infrared radiation sources are used, the beams of which pass at an angle between  $30^\circ$  and  $70^\circ$ , preferably between  $40^\circ$  and  $60^\circ$ , relative to the optical axis of the treatment laser beam. Although the optical axis of the treatment laser beam varies slightly during scanning, it can be considered to be substantially stationary; in particular, it can be considered to be substantially identical to the optical axis of the eye at rest.

According to a further variation of the present invention, a minimum of three radiation sources are provided for the auxiliary beam, the beams of which radiation sources pass at an angle between  $30^\circ$  and  $70^\circ$ , preferably between  $40^\circ$  and  $60^\circ$ , relative to the optical axis of the treatment beam. Again, infrared radiation sources are to be preferred, preferably in the form of light emitting diodes (LEDs), in particular at wavelengths of approximately 810 nm.

Each of the radiation sources mentioned can also comprise a plurality of LEDs. In this case, a "radiation source" within the meaning of this application is a system of a plurality of LEDs which are physically rigidly connected to one another and the combined radiation of which is focused from substantially the same direction onto the eye.

An especially favorable feature provided for is that the radiation sources form a triangle under which the eye to be treated can be positioned. The triangle mentioned may be located in a horizontal plane or in a plane which, relative to the horizontal plane, is slightly inclined. In this context, it should be pointed out that the terms "horizontal" and "vertical" are used in their conventional meaning, i.e., assuming that the reclining patient is lying in a horizontal position. Since, for the present purposes, the electromagnetic radiation can be considered to be independent of the gravitation, and the patient can basically be placed in any position, the terms "horizontal" and "vertical" as used here simply serve as a general explanation, on the assumption, however, that the patient is reclining in a conventional position and that his/her face and thus his/her eye faces upward.

If a minimum of three radiation sources are used for the illuminating auxiliary beam, one embodiment of the present invention that is to be preferred provides that the beams of a minimum of two radiation sources are directed at an acute angle onto the eye to be treated. This acute angle may measure, e.g., between  $30^\circ$  and  $70^\circ$ , preferably between  $40^\circ$  and  $60^\circ$ . In a

particularly useful embodiment of this particular variation of the present invention, it is provided that the beam of a third radiation source, when projected onto a horizontal plane, passes approximately in the direction of the bisectrix of the acute angle mentioned between the other two beams.

Below, a practical example of the present invention will be explained in greater detail on the basis of the drawings. As can be seen:

Figure 1 is a diagrammatic representation of a vertical section through an eye that is to be treated as well as the setup of several radiation sources for the auxiliary beam, and

Figure 2 is a top view of the device with three radiation sources for the auxiliary beam.

Figure 1 shows an eye to be treated 10 with a lens 12, an iris 14, and a cornea 16. In Figure 1, the area 16a to be treated by means of a laser beam (e.g., an excimer laser beam with a wavelength of 193 nm) of cornea 16 is hatched.

Figure 1 is a vertical section through eye 10. Figure 2 shows a top view of the eye to be treated 10 and of the setup of three radiation sources 20,22,24 for the auxiliary beam which serves to determine the ocular position. In the figures, the camera system and the actual treatment laser beam are not separately shown. They correspond to the prior art mentioned above. The following description will therefore be limited to the auxiliary beam and its setup relative to the eye.

Each of the radiation sources 20,22,24 comprises a plurality of individual light-emitting diodes (LEDs) 26. The LEDs emit radiation in the infrared range with a wavelength of 810 nm. For the camera (not shown), a daylight filter is used. The camera used can be, e.g., a black and white camera. To obtain good measuring results with respect to the ocular position, it is important that a high contrast between the pupil (dark) and the iris (light) is achieved. This is ensured by the aforementioned auxiliary beam of radiation sources 20,22,24.

In the practical example shown, each radiation source 20,22,24 comprises twelve individual IR LEDs which are interconnected to an array of 3 x 4 LEDs. In Figure 1, one of the radiation sources (radiation source 24) is shown in such a way that the individual LEDs 26 are clearly visible. The two outer rows of LEDs, each of which comprises four LEDs, e.g., have a transmission angle of  $\pm 8^\circ$  while the middle row of four LEDs has a transmission angle of  $\pm 20^\circ$ . The transmission angle mentioned corresponds approximately to the angle of divergence of the transmission cone. By using the transmission angles mentioned, it is possible to mix the radiation within one array, which has been shown to be useful with respect to a homogeneous illumination which is also free from shadows. It is recommended that in all three radiation sources 20,22,24, different transmission angles be used within each radiation source.

The beams produced from the individual radiation sources are concentrated to form a composite beam 30,32,34. Figures 1 and 2 show the beams thus being generated in their position relative to one another as well as in their position relative to the eye to be treated 10.

With the patient lying in the horizontal position as seen in Figure 2, the actual treatment laser beam (not separately shown) runs perpendicular to the plane of the drawing; its axis is designated by numeral 18. The illuminating beams (auxiliary beams) 30,32,24 run at a slight slope with respect to the horizontal plane and at an angle  $\alpha$  relative to axis 18 of the laser treatment beam. Figure 1 shows the angles between the illuminating beams 30,32 and the treatment laser beam 18, i.e., angles  $\alpha_1$  and  $\alpha_2$ . The same applies to the third radiation source 24. Angles  $\alpha_1$ ,  $\alpha_2$  measure between  $40^\circ$  and  $60^\circ$ . Distance D between the exit opening of illuminating beams 30,32,24 and the peak plane of the cornea to be treated measures between approximately 20 and 150 mm, preferably between approximately 30 and 100 mm.

An especially useful feature resulting from the described slanted incident radiation of the illuminating beam is that the IR light enters outside the treatment area 16a. This ensures that during the treatment, the conditions for the illuminating beam do not change to any significant degree. During the treatment, the transmission of the cornea within treatment area 16a can change dramatically. Using the illuminating system described and shown in Figures 1 and 2, such a change does not have a significant effect on the illuminating beam and thus on the determination of the ocular position. In addition, interfering but unavoidable reflexes of the IR illuminating beam on the surface of the cornea are shifted into the peripheral region of the cornea where they do not interfere with the evaluation of the contour of the pupil as determined.

Figures 1 and 2 also show a useful setup of the radiation sources relative to one another. Two radiation sources 20,22 are positioned in such a way that, when projected onto a horizontal plane, the illuminating beams 30,32 emitted by said radiation sources form angle  $\beta$ . This angle  $\beta$  is an acute angle, preferably in a range from  $25^\circ$  to  $70^\circ$ , especially in a range from  $35^\circ$  to  $65^\circ$ . The third radiation source 24 is subsequently positioned in such a way that its beam 34 runs approximately in the region of bisectrix 36 of angle  $\beta$  between the other two beams. This ensures optimum illumination and optimum results with respect to a determination of the ocular position during the evaluation of the images taken with the camera.

### Claims

1. A device for the medical treatment and/or surgery of the eye with a laser beam, using an auxiliary beam to determine the ocular position, characterized by the fact that a minimum of two infrared radiation sources (20,22,24), the beams (30,32,34) of which run at an angle  $\alpha$  in a



range from  $30^\circ$  to  $70^\circ$  with respect to the optical axis (18) of the treatment and/or surgical beam, are provided for the auxiliary beam.

2. The device for the medical treatment and/or surgery of the eye with a laser beam, using an auxiliary beam to determine the ocular position, characterized by the fact that a minimum of three infrared radiation sources (20,22,24), the beams (30,32,34) of which run at an angle  $\alpha$  in a range from  $30^\circ$  to  $70^\circ$  with respect to the optical axis (18) of the treatment and/or surgical beam, are provided for the auxiliary beam.

3. The device as claimed in Claim 1 or 2, characterized by the fact that the angle ( $\alpha$ ) measures between  $40^\circ$  and  $60^\circ$ .

4. The device as claimed in Claim 2 or 3, characterized by the fact that the radiation sources (20,22,24) form a triangle under which the eye to be treated (10) can be positioned.

5. The device as claimed in one of Claims 2 to 4, characterized by the fact that the beams (30,32) of two radiation sources (20,22) are directed at an acute angle  $\beta$  onto the eye to be treated (10).

6. The device as claimed in Claim 5, characterized by the fact that the beam (34) of a third radiation source (24), when projected onto a horizontal plane, is passing in the direction of the bisectrix (36) of the acute angle.

Including 2 pages of drawings

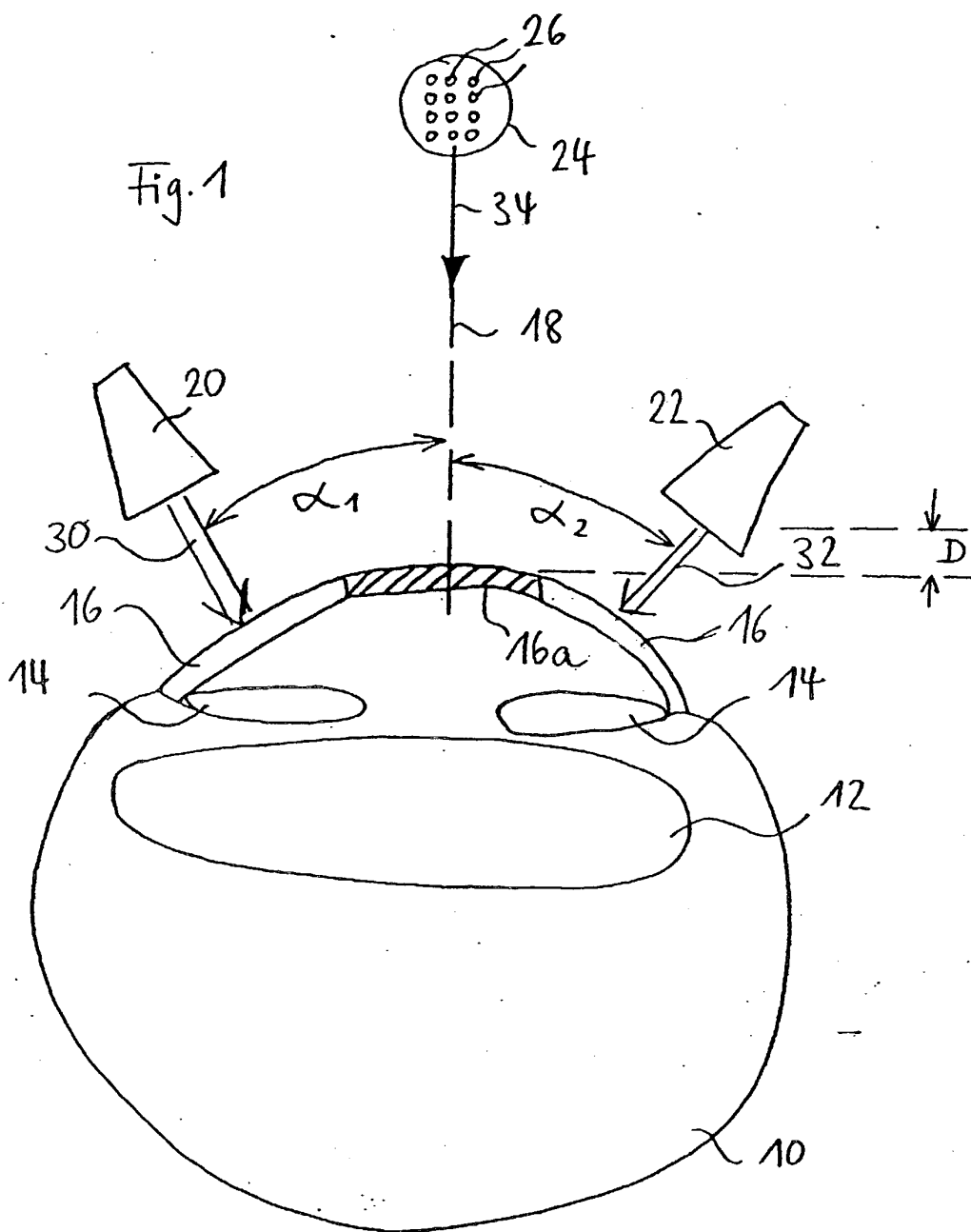


Fig. 2

